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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/663,226	09/16/2003	John R. Boehringer	B1256/20003 (11)	2118

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EXAMINER

HAND, MELANIE JO

ART UNIT	PAPER NUMBER
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3761

NOTIFICATION DATE	DELIVERY MODE
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12/12/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@crbcp.com

Office Action Summary

Application No.

10/663,226

Applicant(s)

BOEHRINGER ET AL.

Examiner

MELANIE J. HAND

Art Unit

3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period **will** apply and **will** expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply **will**, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 September 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 and 35-42 is/are pending in the application.
- 4a) Of the above claim(s) 1-22,30-33,35-38 and 40-42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23-29,39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed September 15, 2008 have been fully considered but they are not persuasive. As to applicant's argument that the syringe cannot supply continuous suction as recited in claim 23, applicant is again referred to Col. 3, lines 35-39, where Svedman explicitly discloses that the plunger both supplies irrigation fluid and drains the wound cavity. It is examiner's position that the drainage of the wound cavity cannot be accomplished without continuous suction, and applicant has not recited a time period for the term "continuous". Any application of suction is continuous in and of itself. As to applicant's argument that Svedman discloses a cylindrical piece of fabric and thus does not anticipate an anisotropic wound packing, the suction forces in the direction orthogonal to suction flow, regardless of which direction or axis of the cylinder the flow is applied to, will necessarily be significantly smaller than the suction forces in the direction of flow. Thus, the contraction due to the suction forces will differ in the direction orthogonal to the flow compared to the direction of flow. This is true of practically any material to which suction is applied and is certainly true of a cylindrical roll where the area over which the forces act is substantially different in each of the different dimensions the cylindrical roll extends, as a cylinder is by its nature larger in one dimension and substantially smaller in the second.
2. Applicant's arguments with regard to dependent claims 24-29 and 39 have been fully considered but are not persuasive, as applicant's arguments depend entirely on arguments regarding the rejection of claim 23, which have been addressed *supra*.

Claim Rejections - 35 USC § 102

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. Claims 23, 27 and 39 are rejected under 35 U.S.C. 102(b) as being anticipated by Svedman (U.S. Patent No. 5,358,494).

With respect to **claim 23**: Svedman teaches a medical device for treating a wound of a patient, the wound having at least one axis extending generally parallel to the skin of the patient contiguous with the wound. With regard to (a), the device comprises suction means arranged for applying continuous suction to the wound in the form of a syringe 12, inasmuch as Svedman discloses that the syringe is used to drain the wound and any interval of suction application is continuous in and of itself. With regard to the limitation "suction means for applying suction to the wound" applicant has disclosed a wall suction device or portable suction pump for applying suction interpreted herein as the means for applying suction. Svedman teaches a portable suction pump in the form of syringe 12. (Col. 3, lines 35-39) With regard to the limitation "to facilitate continuous contraction of the wound", since Svedman teaches a suction means that anticipates the claimed suction means for applying continuous suction, the suction means of Svedman facilitates continuous contraction of the wound. With regard to (b), Svedman teaches an enclosure formed by flexible plate 1. The enclosure of Svedman is coupled to said source of suction 12 and engages the skin around the wound via adhesive layer 3, thus necessarily being arranged for maintaining continuous suction on the wound by engaging the skin of the patient around the wound. (Fig. 1, Col. 2, lines 34-38) With regard to (c), Svedman teaches an anisotropic wound packing means in the form of a flexible pad 11 arranged for placement in the wound. Pad 11 comprises a cylindrical piece of synthetic fabric which is considered herein to be

Art Unit: 3761

anisotropic as it is considerably more difficult to contract a roll of fabric via suction in directions that are orthogonal to the direction of suction flow. (Col. 2, lines 56-58) Thus, wound packing 11 is arranged for preferential contraction along said axis in response to the application of suction to the wound, i.e. the direction parallel to the direction of suction flow. With regard to the limitation "the device being arranged for encouraging the contraction of the wound along an axis", Svedman anticipates the limitations of claim 23 as to an anisotropic wound packing and suction means. A wound will necessarily contract only as quickly as the packing filling the wound and removing fluid therefrom is not obstructing the tissue, thus controlling the direction of contraction of the packing by providing an anisotropic packing and applying suction will necessarily encourage wound contraction along the axis parallel to the direction of contraction. Thus, the device of Svedman is arranged for encouraging wound contraction along said axis.

With respect to **claim 27**: The phrase "generally spirally wound" is not clearly and explicitly defined in the disclosure by applicant. Thus the claim is given its broadest reasonable interpretation. The generally cylindrical gauze roll suggested by Svedman is considered herein to be generally spirally wound inasmuch as it is formed by winding the fabric at least once to form the cylinder. Thus, the device of Svedman renders the limitation "said packing comprises at least one generally spirally wound gauze roll" obvious.

With respect to **claim 39**: Svedman teaches a method of controlling the direction of contraction of a wound of a patient, the wound having at least one axis extending generally parallel to the skin of the patient contiguous with the wound. With regard to (a), the method comprises the step of placing an anisotropic wound packing in the form of a flexible pad 11 arranged for placement in the wound. Pad 11 comprises a cylindrical piece of synthetic fabric which is considered herein

to be anisotropic as it is considerably more difficult to contract a roll of fabric via suction in directions that are orthogonal to the direction of suction flow (Col. 2, lines 56-58) in said wound in a predetermined orientation that preferentially allows a controlled strain to be imposed on the wound tissue. With regard to (b), the method disclosed by Svedman comprises the step of sealing said wound with said packing and a flexible plate 1 to produce an enclosed space contiguous with the wound. (Fig. 1, Col. 2, lines 34-38) With regard to (c), Svedman teaches applying suction to the enclosed space and said wound by suction means 12 and maintaining suction therein whereupon contraction along said wound axis is encouraged necessarily as a resulting of executing the step of application of suction to the wound and the anisotropic packing.

Claim Rejections - 35 USC § 103

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
6. Claims 24-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Svedman (U.S. Patent No. 5,358,494).

With respect to **claim 24**: Svedman teaches that the packing comprises a cylindrical piece of synthetic fabric. Svedman does not explicitly teach gauze. However it is well known in the art to roll up gauze into a cylindrical configuration and place it in a wound to absorb wound exudate. Therefore, it would be obvious to modify the device of Svedman such that the cylindrical piece of synthetic fabric is a roll of gauze with a reasonable expectation of success to facilitate healing of a wound by absorbing wound exudate.

Art Unit: 3761

With respect to **claim 25**: The packing means fairly suggested by Svedman comprises at least one generally cylindrical gauze roll necessarily having a generally longitudinal axis and radial axes. The longitudinal axis of the roll will necessarily face outwardly from the wound and the radial axes of the roll will necessarily face sides of the wound, regardless of the position in which the roll is oriented within the wound. The motivation to modify the device of Svedman such that the wound packing is a cylindrical piece of gauze is stated *supra* with respect to claim 24.

With respect to **claim 26**: Svedman does not explicitly teach that the packing comprises a plurality of said cylindrical gauze rolls to be disposed with their respective longitudinal axes generally parallel to each other in the wound. However, a plurality of rolls would accomplish the same result as one roll. It would be obvious to one of ordinary skill in the art to modify the device of Svedman such that the packing 11 comprises a plurality of identical gauze rolls identical to the first roll suggested by Svedman with a reasonable expectation of success to provide an effective means of packing a wound. It has been held that the mere duplication of the essential working parts of a device involves only routine skill in the art. *St Regis paper Co. v. Bemis. Co.* 193 USPQ 8 (7th Cir. 1977) Thus the device suggested by Svedman renders the limitation "to be disposed with their respective longitudinal axes generally parallel to each other in the wound" obvious. Further this limitation is directed to a method of using the packing that bears little patentable weight herein, as claim 26 is directed to an article.

7. Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Svedman ('494) in view of Zamierowski (U.S. Patent No. 4,969,880).

Art Unit: 3761

With respect to **claim 28**: Svedman teaches a portable suction means, “e.g. a syringe”, but does not explicitly a flexible bulb. Zamierowski teaches a wound treatment device comprising an apparatus adapted for manual compression, comprising a flexible bulb 42, with an inlet conduit in the form of suction tube 41 connecting the bulb 42 to the wound enclosure 22 and an outlet conduit 34 connecting the bulb to discharge in the form of pumping medication to wound site 12. Since a flexible bulb and a syringe are both equally effective and equally well known portable means for applying suction, it would be obvious to one of ordinary skill in the art to modify the device of Svedman so as to replace the syringe with a flexible bulb with a reasonable expectation of success to provide an equally effective portable source of suction to allow the device to be used in more various ways and locations.

8. Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Svedman ('494) in view of Zamierowski ('880), as applied to claim 28 above, and further in view of McNeil (U.S. Patent No. 4,551,141).

With respect to **claim 29**: Svedman does not teach a flexible bulb. Zamierowski teaches a flexible bulb but does not teach spring means inside the bulb. McNeil teaches that springs are an equivalent means of generating suction to bellows and bulbs in portable drainage devices, both of which are also taught by Zamierowski. Therefore it would be obvious to one of ordinary skill in the art to modify the suction means of the combines teaching of Svedman and Zamierowski so as to have a bulb with a spring means inside to supplement the suction-generating capability of the bulb as taught by McNeil. The limitation of “for providing resistance to rapid decay of suction in the bulb” constitutes functional language that is given little patentable weight herein. ('141, Col. 6, lines 59-62) The combined teaching of Svedman and

Zamierowski and McNeil renders all of the remaining limitations of claim 29 obvious and thus is fully capable of providing resistance to rapid decay of suction in the bulb.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELANIE J. HAND whose telephone number is (571)272-6464. The examiner can normally be reached on Mon-Thurs 8:00-5:30, alternate Fridays 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melanie J Hand/
Examiner, Art Unit 3761